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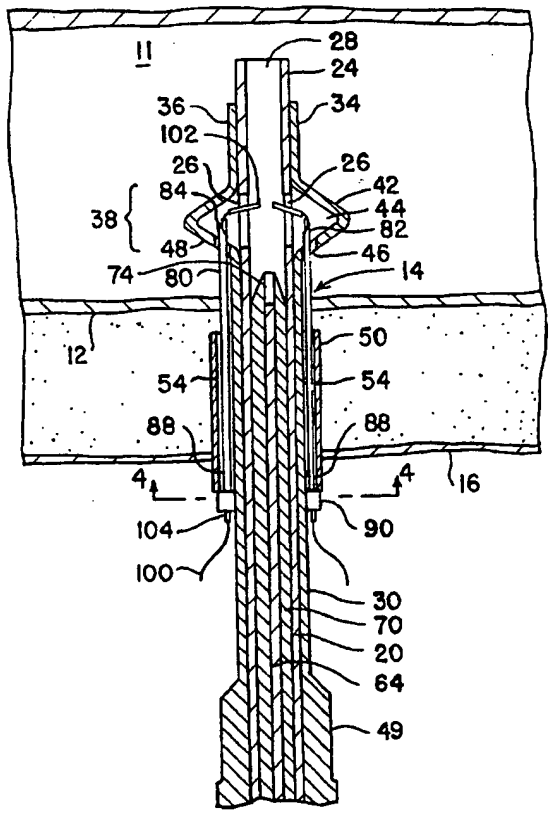
(57) Abstract

An assembly (10) is provided for suturing an incision in a tissue wall of a patient. The assembly comprises a first elongated member (20) having a hollow portion and an opening through a sidewall adjacent the hollow portion. The assembly may further comprise a second elongated member (30) positioned about the first elongated member and having an access hole therethrough, and a needle (80) insertable through both the tissue wall and the access hole (46) to provide a pathway for insertion of the suture material through the opening and into the hollow portion. The second elongated member includes an expandable portion to define a cavity in alignment with the opening. Such expandable portion may comprise longitudinal slits (40) which expand to form wings (42). A third member is positioned on the second member and includes a lumen for guiding the needle toward the access hole in the second member.



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CATHETER INTRODUCER WITH SUTURE CAPABILITY

FIELD OF THE INVENTION

The present invention relates to medical devices for closing incisions and, more particularly, to a catheter introducer capable of assisting in threading a suture material through a tissue wall surrounding an incision and withdrawing the suture material back through the incision.

BACKGROUND OF THE INVENTION

Catheter introducers are routinely used for access to the arterial system, providing a means of entry into the interior of an artery while inhibiting blood loss during catheter procedures. For example, catheter introducers are used for introduction of balloon angioplasty catheters into the femoral artery of a patient for access to the coronary arteries via the ascending and descending aorta to perform percutaneous transluminal coronary angioplasty.

Catheter introducers typically comprise an elongated tubular member open at both ends, a tubular dilator slidably positionable within the tubular member, and a guidewire slidably positionable within the dilator. Catheter introducers can be introduced into an artery utilizing a standard insertion procedure, such as the Seldinger technique. In the Seldinger technique, the artery wall is pierced by a stylet and cannula, the stylet is removed, the guidewire is inserted through the cannula, and the cannula is removed from the artery. The introducer, comprising the elongated tubular member and dilator

assembly, is then introduced over the guidewire until the distal tip of the elongated tubular member is positioned within the artery. The dilator and guidewire are subsequently removed to allow standard catheter procedures to be performed (e.g., coronary angiography or percutaneous transluminal coronary angioplasty).

On completion of the catheter procedure, the elongated tubular member is removed from the artery, leaving an arterial incision (i.e., in the wall of the artery) below the skin line. This incision can be the source of blood loss, hematoma and other complications. Closure of such incisions by standard suturing procedures (i.e., needle and thread) is complicated by the depth of the arterial incision below the skin line. Consequently, the current practice is to stop bleeding by the application of pressure to the incision, either manually or by a clamping device, or by the insertion of a plugging member into the incision to inhibit blood loss therefrom. Such current techniques can be costly due to the required medical staff time to perform the procedures, and can result in prolonged recovery times and patient discomfort.

SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide an apparatus and method for effectively suturing an incision in a tissue wall of a patient without the need for invasive surgery.

It is a further object of the present invention to provide an invasive medical device in which suture material can be threaded through a tissue wall in a patient and into an interior of the device while the device remains in the incision.

The present invention is embodied in an assembly particularly adapted to facilitate threading of a suture material through a tissue wall of a patient and withdrawing the suture material back through an incision which was created for performing a medical procedure. The assembly includes a first elongated member having a hollow portion and at least one opening through a sidewall adjacent the hollow portion. The first elongated member is positionable through the incision with the opening being inside the tissue wall of the patient. Means for inserting a suture material through the tissue wall and through the opening of the first elongated member is provided, whereby the suture material may subsequently be withdrawn back through the incision. When multiple sutures are threaded in this manner on opposing sides of the incision, the sutures can be tied together by known techniques to effectively close the incision.

The means for inserting may preferably include a second elongated member positioned about the first elongated member and having an access hole therethrough. The second elongated member may include an expandable portion selectably expandable from a retracted diameter to an expanded diameter larger than the retracted diameter to

create a cavity between the first and second elongated members. Preferably, distal movement of a second proximal end of the second elongated member relative to a first proximal end of the first elongated member results in expansion of the expandable portion. More preferably, a second distal end of the second elongated member is secured to a first distal end of the first elongated member and the second proximal end is slidable relative to the first proximal end. The second elongated member may further include longitudinal slits through the expandable portion, whereby distal movement of the second proximal end relative to the first proximal end results in expansion of the expandable portion to form wing portions defining the cavity.

The cavity is preferably positioned over the opening of the first elongated member and in alignment with the access hole, such that an access path for the suture material (i.e., from the exterior of the assembly to the hollow portion in the first elongated member) is formed. For example, the means for inserting the suture material may insert the suture material through the tissue wall, access hole, cavity, and opening to position at least a portion of the suture material in the hollow portion of the first elongated member. In addition, to provide a means for securing the suture material within the assembly, the access hole may be misaligned with the openings when the second elongated member is the retracted position.

The means for inserting may further comprise at least one needle insertable through the tissue wall and through the access hole in the second elongated member. Such a needle may facilitate introduction of the suture material into the hollow portion (e.g., by having the suture material detachably secured to the needle during insertion of the needle through the tissue wall and access hole). Preferably, the needle is hollow and thereby provides a pathway through which the suture material may be introduced. Introduction of the suture material through the hollow needle may be facilitated by utilizing a suture material having a guide tip (e.g., a flexible guidewire tip) integral therewith and further by utilizing a cannula for pushing the guide tip (including the suture material) through the hollow needle and into the hollow portion of the first elongated member.

When used with an assembly having first and second elongated members forming a cavity, the hollow needle may be inserted through the tissue wall of the patient and through the access hole to position a tip of the hollow needle in the cavity formed by the wing portion. When the suture material (e.g., having a guide tip) is inserted through the hollow needle, the wing portion acts to deflect the suture material (e.g., the guide tip) into the opening.

The assembly may further comprise a third member positioned about the second elongated member and having at least one lumen extending therethrough for receiving and guiding the needle toward the access hole. The lumen is

preferably positioned parallel to the first and second elongated members and in alignment with the access hole when the expandable portion is expanded. The third member may also be movable axially relative to the second elongated member in order to accommodate varying depths of the tissue wall below the skin line.

To withdraw the suture material back through the incision, the assembly may further comprise a means for engaging the suture material within the hollow portion, whereby removal of the means for engaging from the first elongated member will result in withdrawal of the suture material back through the incision. Such means may, for example, include an engaging member positionable within the hollow portion and having a mechanical grip (e.g., a clamp, snare or other device), adhesive layer, or magnet (e.g., if the guide tip is metallic) on one end thereof for engaging the suture material (e.g., guide tip).

Alternatively, the suture material may be withdrawn from the incision by securing the suture material within the hollow portion of the first elongated member and removing the first elongated member from the incision. It may be necessary to provide a separate means for securing in order to prevent the suture material from sliding out of the hollow portion during removal of the first elongated member. Such means may comprise a fourth member slidably positionable within the hollow portion of the first elongated member. More specifically, after the suture material is properly positioned within the hollow portion,

the fourth member may be advanced toward the opening to restrict the suture material (e.g., the guide tip) between the fourth member and the sidewall of the first elongated member to thereby prevent the suture material from sliding out of the hollow portion when the first elongated member is removed from the incision. Alternatively, the means for securing may comprise an expandable member positionable within the hollow portion and expandable to secure the suture material (e.g., the guide tip) within the hollow portion. Preferably, the fourth member (and/or expandable member) also acts as a vessel dilator on introduction of the assembly into the artery.

In one embodiment, the invention comprises an arterial catheter introducer comprising a hollow first tube for introducing a catheter into an artery, a dilator for facilitating insertion of the first tube into an arterial incision, and a guidewire for guiding the dilator and first tube into the incision. Such an introducer may be used to perform transluminal coronary angioplasty procedures prior to closure of the incision utilizing the features of the present invention. The first tube is provided with two openings positioned on opposing sides thereof near the first distal end. A second tube is positioned around the first tube and is secured to the first tube at the distal ends thereof, but is slidable relative to the first tube at the proximal ends thereof.

The second tube is further provided with four longitudinal slits defining an expandable portion proximal

to the first distal ends. Upon distal movement of the second proximal end relative to the first proximal end, the material between the four longitudinal slits expands to define four wing portions, two of which are aligned with the openings in the first tube. The expandable portion further includes two access holes on proximal portions of the two aligned wing portions. A third member is positioned around the second tube proximal to the expandable portion and defines lumens on opposing sides of the second tube approximately parallel to the first and second tubes. The lumens are designed to slidably receive and guide the hollow needles toward the access holes in the expandable portion when the expandable portion is expanded.

As will be appreciated, because suture material can be threaded through a tissue wall below the skin layer while the medical device is in the incision, the present invention allows suturing of subepidermal incisions without excessive fluid loss therefrom and without the need for invasive surgical procedures. Furthermore, the suturing which can be accomplished utilizing the present invention substantially reduces the need to apply pressure to the incision or to insert a plugging member therein to remedy blood loss, hematoma and other complications.

These and other features, advantages and objects of the present invention will be further understood and appreciated by those skilled in the art by reference to the following written specification, claims and appended drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded assembly view of an apparatus embodying the present invention;

Fig. 2A is a longitudinal section taken along line 2-2 in Fig. 1 with the apparatus inserted into an incision in an artery wall;

Fig. 2B is the section view of Fig. 2A with the apparatus in the expanded position;

Fig. 2C is the side view of Fig. 2A showing the suture material inserted into the artery;

Fig. 2D is the section view of Fig. 2A with the apparatus in the retracted position and the suture material retained within the interior of the first tube;

Fig. 2E is the section view of Fig. 2A showing the apparatus withdrawn from the incision to thereby pull the suture material back through the incision;

Fig. 2F is the section view of Fig. 2A showing the suture material threaded through the artery wall after the suture material is cut from the apparatus.

Fig. 3 is a section view taken along line 3-3 in Fig. 1;

Fig. 3A is the section view of Fig. 3 showing an alternative embodiment of the positioning member.

Fig. 4 is a section view taken along line 4-4 in Fig. 2C showing details of the contoured stop members.

Fig. 5 is an exploded assembly view of an insertion needle and insertion cannula for introducing a guidewire into an artery.

DETAILED DESCRIPTION

Figs. 1-4 illustrate an arterial catheter introducer embodying the features of the present invention. Although this embodiment of the present invention will be described with reference to a catheter introducer, it should be appreciated that the present invention is also applicable to other invasive medical devices wherein it is desirable to close an incision left by the device. For example, the present invention could be used with a trocar assembly used in laparoscopic surgery to close an incision created by the trocar assembly or with a gastrostomy feeding tube to close an incision created by the feeding tube.

For ease of description, in the discussion of the apparatus 10, the term "distal" refers to the direction toward the patient (e.g., the direction toward the top of the page in Figs. 2A-2F). Correspondingly, the term "proximal" refers to the direction away from the patient (e.g., the direction toward the bottom of the page in Figs. 2A-2F).

Referring to Fig. 1, the apparatus 10 generally comprises a first tube 20 for introducing a catheter (not shown) into an artery, a second tube 30 positioned around the exterior of the first tube 20, and a positioning member 50 positioned around the exterior of the second tube 30. A dilator 70 and guidewire 64 are provided for facilitating insertion of the first and second tubes 20, 30 into an artery and for achieving and maintaining access to the artery during the suturing procedure of the present

invention. A sidearm tube 60 with a stopcock 62 extends from a proximal end 22 of the first tube 20 for fluid withdrawal or medication injection. The apparatus 10 further includes hollow needles 80, guide tips 102 attached to suture material 100, and hollow cannulas 104 for introducing the suture material 100 through the artery wall 12 and into the interior of the first tube 20.

Referring to Fig. 2A-2E, the first tube 20 of the present embodiment is an elongated, hollow cylindrical member open at both a first proximal end 22 and a first distal end 24 and having a central longitudinal axis 18. Because the present embodiment will be used as an arterial catheter introducer, the interior 28 of the first tube 20 should have a diameter large enough for insertion of a catheter appropriately sized for the specific application. For example, interior diameters of such catheter introducers are typically in the range of .065 inches to .117 inches (5 French to 9 French) and, for femoral artery applications, are preferably at least about .079 inches (6 French).

The first tube 20 is provided with two openings 26 positioned on opposing sides thereof (i.e., 180° from each other) near the first distal end 24. These openings 26 allow access to the interior 28 of the first tube 20 by the suture material 100, as will be explained herein in more detail. Such openings 26 are generally oblong-shaped with the longer dimension being aligned with the longitudinal axis 18. Such oblong shape facilitates insertion of the

cylindrically-shaped guide tips 102 therein, as will be described below in more detail. For the present embodiment, the openings 26 have dimensions of approximately 0.060 inches by .250 inches. The first tube 20 is preferably made from a polymer-based material such as polyolefin, polytetraflouroethylene, polyurethane and, most preferably, polyethylene.

Means for inserting the suture material 100 is provided for getting the suture material 100 inside the first tube 20. In the disclosed embodiment, such means for inserting includes a second tube 30 positioned over the first tube 20 and generally concentric therewith (i.e., the second tube 30 has the same central longitudinal axis 18 as the first tube 20). Similar to the first tube 20, the second tube 30 is an elongated, hollow cylindrical member with an interior diameter slightly greater than the exterior diameter of the first tube 20 such that when the second tube 30 is positioned over the first tube 20 there is a slidable fit therebetween. For example, in the present embodiment, the interior diameter of the second tube 30 is about .134 inches and the exterior diameter of the first tube 20 is about .130 inches. A second distal end 34 of the second tube 30 is secured to the first distal end 24 of the first tube 20 at a secured portion 36 located distal to the openings 26 in the first tube 20. Correspondingly, the remainder of the second tube 30 (proximal to the secured portion 36) is slidable relative to the first tube 20.

Four longitudinal slits 40 are provided to define an expandable portion 38 of the second tube 30 proximal to the secured portion 36 and aligned with the openings 26 in the first tube 20. The slits 40 are designed such that distal sliding movement of the second proximal end 32 relative to the first tube 20 in a telescoping manner results in the expandable portion 38 of the second tube 30 moving radially outward to form four wings 42, as shown in Fig. 2B. Such radial outward movement of the expandable portion 38 effectively expands the expandable portion 38 from a retracted diameter, shown in Fig. 2A, to an expanded diameter, shown in Fig. 2B, larger than the retracted diameter. The extent to which the expandable portion 38 increases in diameter is proportional to the length of the longitudinal slits 40. That is, the longer the slits 40, the greater the increase in diameter of the expandable portion 38. In the present embodiment, the slits 40 are about .250 inches long, resulting in expansion of the expandable portion 38 from about .150 inches to about .275 inches.

The provision of a second tube 30 having an expandable portion 38 serves several useful functions. For example, the expandable portion 38 provides a back support behind the artery wall 12 to facilitate piercing of the artery wall 12 by the hollow needles 80, as described in more detail below. Also, the expandable portion 38 creates a cavity 44 over the openings 26 to deflect the guide tips 102 from the hollow needles 80 toward the openings 26, as

described below. In addition, when in the expanded condition, the expandable portion 38 inhibits inadvertent withdrawal of the apparatus 10 from the incision 14 during suturing procedures. The ability to expand and retract is especially preferable because it allows the apparatus 10 to be inserted and withdrawn from the incision 14 in the retracted condition, thereby reducing the need to undesirably enlarge the incision 14.

Two of the wings 42 are aligned with the openings 26 in the first tube 20 such that, when they are expanded, they define generally triangular-shaped cavities 44 over the openings 26 and into which the suture material 100 will be introduced, as described below. It should be appreciated that, by proper material selection, the expandable portion 38 could expand into a bulge, similar to a rivet, rather than wings 42, without the need for the longitudinal slits 40. Similar to the first tube 20, the second tube 30 preferably comprises a polymer-based material such as polyolefin, polytetraflouroethylene, polyurethane and, most preferably, polyethylene.

Access holes 46 are provided in the proximal portion 48 of the two aligned wings 42 to facilitate access to the cavities 44 by hollow needles 80, as described below. Preferably, the access holes 46 are aligned parallel to the longitudinal axis 18 when the expandable portion 38 of the second tube 30 is fully expanded to form the wings 42. Furthermore, it is preferable that the access holes 46 are misaligned with the openings 26 in the

first tube 20 when the expandable portion is retracted. That is, the access holes 46 are proximal to the openings 26 in the retracted position and do not overlap therewith. Such positioning of the access holes 46 relative to the openings 26 effectively restricts the suture material 100 (e.g., the guide tip 102) when the wings 42 are retracted, thereby retaining the suture material 100 (e.g., the guide tip 102) in the interior 28 of the first tube 20 when the apparatus 10 is being withdrawn from the incision 14.

A hemostasis valve contained within a fitting 49 is secured to the second proximal end 32 in order to inhibit blood leakage between the first tube 20 and the second tube 30. The fitting 49 also serves as a grip which the user of the device can readily hold to provide distal movement of the second proximal end 32 relative to the first proximal end 22 to expand the expandable portion 38, as described above.

The means for inserting in the disclosed embodiment further includes a positioning member 50 positioned about the second tube 30. The positioning member 50 is an elongated hollow member having an oblong cross-section. A central portion 52 of the cross-section follows a generally cylindrical shape with an inner diameter approximately equal to the outer diameter of the second tube 30 (e.g., about .150 inches in the present embodiment). The central portion 52 of the positioning member 50 is secured to the second tube 30 at a location proximal to the expandable

portion 38 of the second tube 30. Alternatively, the positioning member 50 could be slidable axially relative to the second tube 30 to account for different depths of the arterial incision 14 relative to the skin line 16 of the patient.

As shown in Figs. 3 and 4, the oblong shape of the positioning member 50 defines lumens 54 on opposing sides of the second tube 30 (i.e., 180° from each other) travelling the length of the positioning member 50. The lumens 54 extend approximately parallel to the longitudinal axis 18 and are in alignment with the access holes 46 in the wings 42 of the second tube 30 when the wings 42 are fully expanded. The lumens 54 are sized to slidably receive the hollow needles 80 therein and function to align the hollow needles 80 relative to the access holes 46. Similar to the first and second tubes 20, 30, the positioning member 50 preferably comprises a polymer-based material such as polyolefin, polytetraflouroethylene, polyurethane and, most preferably, polyethylene.

Alternatively, it should be appreciated that the lumens 54 could be separate, cylindrically-shaped passageways 54a formed through the positioning member 50 on opposing sides thereof, as shown in Fig. 3A. In such an arrangement, the diameter of the passageways 54a may be slightly larger than the diameter of the hollow needles 80 to facilitate sliding interaction therebetween. Similar to the arrangement shown in Fig. 3, the passageways 54a extend approximately parallel to the longitudinal axis 18 and are

in alignment with the access holes 46 in the wings 42 of the second tube 30 when the wings 42 are fully expanded. As with the lumens 54, the passageways 54a function to align the hollow needles 80 relative to the access holes 46.

The dilator 70 is an elongated, hollow cylindrical member having an outer diameter slightly smaller than the inner diameter of the first tube 20 (e.g., about .077 inches in the present embodiment) and an inner diameter slightly larger than the introducer guidewire 64 (e.g., about .040 inches in the present embodiment). The dilator 70 is slidably positionable over the introducer guidewire 64 and within the interior 28 of the first tube 20. The proximal end 72 of the dilator 70 is enlarged and extends beyond the first proximal end 22 so that the dilator 70 can be gripped by the user and selectively moved to different positions within the first tube 20. The distal end 74 of the dilator 70 is preferably conically shaped to facilitate insertion of the apparatus 10 into an incision 14 in an artery wall 12. A hemostasis valve contained within a housing 78 is secured to the first proximal end 22 to provide a seal between the dilator 70 and the first tube 20 to inhibit blood leakage therebetween. In addition to performing the functions of a standard dilator 70 (i.e., facilitating insertion of the introducer into the incision 14), the dilator 70 of the present invention also functions as a means for retaining the suture material 100 (e.g., the guide tips 102) within

the first tube 20 as the apparatus 10 is being withdrawn from the incision 14, as described below.

In the alternative, it should be appreciated that the dilator 70 could comprise any means for securing the suture material 100 within the first tube 28. For example, the dilator 70 could comprise an inflatable member selectably positionable within the interior 28 of the first tube 20, such that the inflatable member can be appropriately inflated/expanded to secure the suture material 100 between the inflatable member and the interior 28 of the first tube 20.

Referring now to Fig. 2C, the means for inserting in the disclosed embodiment further includes hollow needles 80 which are utilized to provide access to the cavities 44 formed by the wings 42. As with most medical needles, the distal tips 82 of the hollow needles 80 are beveled to facilitate piercing of the needles through the artery wall 12. The outer diameter of the hollow needles 80 is designed such that the hollow needles 80 can be slidably inserted through the lumens 54 in the positioning member 50 toward the expanded wings 42 of the second tube 30. Because, as noted above, the access holes 46 in the wings 42 are aligned with the lumens 54 in the positioning member 50, further insertion of the hollow needles 80 through the lumens 54 will result in the distal tips 82 of the hollow needles 80 passing through the access holes 46 of the wings 42 and entering the cavities 44.

In use, the apparatus 10 will be positioned in an incision 14 with an artery wall 12 between the positioning member 50 and the expandable portion 38 of the second tube 30. Consequently, the hollow needles 80 will pierce the artery wall 12 as they are being inserted through the lumens 54 toward the access holes 46 in the wings 42. In this regard, it is desirable to rotationally orient the hollow needles 80 such that the beveled face 84 of both distal tips 82 face toward the central longitudinal axis 18. Such an orientation performs two functions. First, it causes the hollow needles 80 to initiate piercing of the artery wall 12 further away from the central longitudinal axis 18, thus providing greater arterial wall 12 to be engaged between the suture material 100 and the incision 14, resulting in less chance for the artery wall 12 to tear when the suture material 100 is tied. Second, orienting the hollow needles 80 in such a position provides a more direct path for the guide tip 102 to follow when entering the interior 28 of the first tube 20, as described below.

In order to insure proper rotational orientation of the hollow needles 80 within the positioning member 50, yet allow the hollow needles 80 to be slidable therein, contoured stop members 90 can be provided on the proximal end 88 of the hollow needles 80. For example, the contoured stop members 90 could comprise an orienting surface 92 which slidably engages and generally follows the contour of the exterior surface of the second tube 30, as shown in

Fig. 4. Such contoured stop members 90 would only allow the hollow needles 80 to be inserted into the lumens 54 in one rotational orientation. Preferably, the orienting surfaces 92 would be aligned with the beveled faces 84 of the hollow needles 80 such that the beveled faces 84 are always facing the central longitudinal axis 18. Furthermore, by properly axially positioning the stop members 90 on the hollow needles 80, the stop members 90 can act to limit the insertion depth of the hollow needles 80 into the lumens 54 to thereby insure that the distal tips 82 of the hollow needles 80 will be properly positioned within the cavities 44 at full insertion. It should be appreciated that, instead of stop members 90, other means for aligning the hollow needles 80 could be used, such as visual marks on the proximal end 88 of the hollow needles 80.

The suture material 100 in the disclosed embodiment includes a guide tip 102 attached to one end thereof to facilitate introduction of the suture material 100 through the hollow needles 80 and into the interior 28 of the first tube 20. The guide tip 102 acts as a lead for guiding the suture material through the hollow needles. Preferably, the guide tip 102 is a flexible cylindrical member that will deflect off of the wings 42 and into the opening 26 and, more preferably, the guide tip 102 comprises a flexible guidewire. Hollow cannulas 104 are utilized for pushing the guide tips 102 through the hollow needles 80. The exterior diameter of the hollow cannulas 104 is slightly

smaller than the interior diameter of the hollow needles 80 such that the hollow cannulas 104 can freely slide inside the hollow needles 80. The interior diameter of the hollow cannulas 104 is large enough to allow the suture material 100 to freely pass therethrough, but is small enough to prevent the guide tips 102 from doing the same.

As an alternative to using hollow needles and cannulas, it should be appreciated that the means for inserting may comprise a non-hollow needle which is detachably connectable to the suture material 100 at the needle tip. In this regard, the needle may be inserted through the artery 12 wall and into the interior 28 of the first tube 20 while the suture material is secured to the needle tip. In this manner, the suture material would be inserted into the interior 28 of the first tube 20 at the same time the needle is being inserted. Accordingly, it would not be necessary to insert the suture material 100 through a hollow needle and may further not be necessary to use guide tips.

Referring to Fig. 2A-2F, the use and operation of the apparatus 10 embodying the present invention will now be described in connection with its use as an arterial catheter introducer inserted into an arterial wall 12 using a Seldinger technique. An insertion stylet 110 and insertion cannula 112 used in the Seldinger technique are shown in Fig. 5. In the Seldinger technique, the insertion stylet 110 is slidably positioned within the insertion cannula 112 such that the insertion stylet tip 114 aligns

with the insertion cannula tip 116. The assembly is then inserted through the artery wall 12 until the insertion stylet tip 114 and cannula tip 116 are inside the artery 11. The insertion stylet 110 is then removed from the insertion cannula 112 and the guidewire 64 is inserted into the insertion cannula 112 until at least a portion of the guidewire 64 is similarly positioned inside the artery 11. The insertion cannula 112 is then removed, leaving only the guidewire 64 extending through the incision 14 into the interior of the artery 11.

With the dilator 70 fully inserted into the first tube 20 such that the distal end 74 of the dilator 70 extends beyond the first distal end 24, the apparatus 10 is threaded over the guidewire 64 (i.e., the dilator 70 is slid over the guidewire 64) and advanced toward the incision 14. Because of its conically-shaped distal end 74, when the dilator 70 reaches the incision 14, the dilator 70 will gradually stretch the incision 14 to facilitate insertion of the first and second tubes 20, 30 therein. The apparatus 10 is further inserted into the incision 14 until the artery wall 12 is positioned between the expandable portion 38 of the second tube 30 and the positioning member 50. That is, the apparatus 10 is positioned such that the openings 26 in the first tube 20 are inside the artery 11, as shown in Fig. 2A. The dilator 70 and guidewire 64 are subsequently removed to perform arterial catheter procedures.

After the catheter procedures have been performed, the dilator 70 and guidewire 64 are reintroduced into the first tube 20. It should be noted that, in order to have access to the proximal end 56 of the positioning member 50, the skin line 16 should be positioned distal to the proximal end 56 of the positioning member 50, as shown in Fig. 2A. In this regard, a positioning member 50 which is axially slidable on the second tube 30 is beneficial in that the positioning member 50 can be slid to accommodate different depths of the artery wall 12 relative to the skin line 16. Preferably, such a slidable positioning member 50 would not be rotatable relative to the second tube 30 so that the lumens 54 in the positioning member 50 remain aligned with the access holes 46 in the wings 42.

In order to perform the suturing procedure of the present invention, the apparatus should be positioned such that the lumens 54 are positioned on opposing sides of the incision. Next, the second proximal end 32 is moved distally relative to the first proximal end 22 to provide expansion of the expandable portion 38 from a retracted diameter to an expanded diameter larger than the retracted diameter, as shown in Fig. 2B. Such expansion results in wings 42 which define cavities 44 positioned over the openings 26 in the first tube 20. The hollow needles 80 are then partially inserted into the lumens 54 defined by the positioning member 50 and, using the contoured stop members 90 on the proximal end 88 thereof, the hollow needles 80 are oriented such that the beveled faces 84 of

the distal tips 82 face toward the central longitudinal axis 18. The hollow needles 80 are further inserted into the lumens 54 to such a depth that the distal tips 82 pierce the artery wall 12 and enter the cavities 44 through the access holes 46, as shown in Fig. 2C. Proper insertion depth of the hollow needles 80 is insured by the stop members 90.

The dilator 70 is subsequently retracted (i.e., moved proximally relative to the first tube 20) until the distal end 74 of the dilator 70 is positioned proximal to the openings 26 in the first tube 20. The guide tips 102 and attached suture material 100 are then inserted through the hollow needles 80 using the hollow cannula 104. Such insertion of the guide tips 102 continues until the guide tips 102 are inserted into the interior 28 of the first tube 20 through the openings 26, as shown in Fig. 2C. Next, the dilator 70 is advanced distally until the suture material 100 (e.g., the guide tips 102) is restricted between the distal end 74 of the dilator 70 and the interior 28 of the first tube 20, as shown in Fig. 2D. The hollow needles 80 and corresponding cannulas 104 are then retracted at least until the distal tips 82 of the hollow needles 80 and cannulas 104 are no longer inside the access holes 46. The expandable portion 38 is subsequently retracted by moving the second proximal end 32 proximally relative to the first proximal end 22. Misalignment of the access holes 46 relative to the openings 26 provides further restricting (i.e., in addition to the restricting

provided by the dilator 70) of the suture material 100 and/or guide tips 102 to retain the suture material 100 in the interior 28 of the first tube 20, as further shown in Fig. 2D.

Subsequent removal of the apparatus 10 from the incision 14 results in the suture material 100 being withdrawn through the incision 14, as shown in Fig. 2E. The two ends of suture material 100 exiting the incision 14 (the inside ends 106) can be tied together and the two ends of the suture material 100 exiting the holes on either side of the incision 14 (the outside ends 108) can subsequently be tied to facilitate closure of the incision 14.

As an alternative to withdrawing the suture material 100 through the incision 14 by removing the apparatus 10 from the incision 14, the suture material 100 could be withdrawn by pulling it back through the interior 28 of the first tube 20. That is, the apparatus 10 could be provided with a means for engaging the suture material 100 and pulling the suture material out of the first tube 20 while the apparatus 10 stays inserted in the incision 14. For example, the means for engaging the suture material 100 may comprise an adhesive coated over the distal tip 74 of the dilator 70, such that the dilator 70 could be inserted into the first tube 20 to engage the suture material 100 and be withdrawn to withdraw the suture material back through the first tube 20 (and therefore back through the incision 14). Similarly, the dilator 70 (or any other member) could be supplied with a magnet or mechanical grip (e.g., a clamp,

snare, or other device) for capturing the suture material 100 (including the guide tip 102) and withdrawing it back through the incision 14.

Because of the distal location of the incision 14 below the skin line 16, the incision 14 is typically not visible to the user of the apparatus 10, as generally represented in Fig. 2F. Accordingly, after removal of the apparatus 10 from the incision 14 and cutting of the suture material 100, as shown in Fig. 2F, it may be difficult for the user of the apparatus 10 to differentiate between the two inside ends 106 from the two outside ends 108 in order to facilitate closure of the incision. Furthermore, for other tieing techniques, it may be desirable to distinguish between the suture material 100 on one side of the incision 14 from the suture material 100 on the other side (i.e., right side versus left side). In order to alleviate the above-noted problems, suture material 100 may preferably be provided in which each of the four ends of suture material 100 is a different color. For example, referring to Fig. 2F, the suture material 100 entering through the artery wall 12 on one side of the incision 14 could be black with a white tip exiting the incision 14, and the suture material 100 entering through the artery wall 12 on the other side of the incision 14 could be blue with a green tip. Use of such suture material would facilitate distinguishing between each of the four ends of suture material 100 to assist in proper closure of the incision 14.

The foregoing description of the present invention has been presented for purposes of illustration and description. Furthermore, the description is not intended to limit the invention to the form disclosed herein. Consequently, variations and modifications commensurate with the above teachings, and the skill or knowledge of the relevant art, are within the scope of the present invention. The embodiments described hereinabove are further intended to explain best modes known for practicing the invention and to enable others skilled in the art to utilize the invention in such, or other, embodiments and with various modifications required by the particular applications or uses of the present invention. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by the prior art.

What is claimed is:

1. An assembly for use in suturing an incision in a tissue wall of a patient with a suture material, said assembly comprising:

a first elongated member having a hollow portion and at least one opening through a sidewall adjacent said hollow portion, said first elongated member being positionable through the incision with said at least one opening positioned distal to the tissue wall;

means, positionable adjacent to said first elongated member, for inserting a suture material through the tissue wall adjacent to the incision and through said at least one opening while said first elongated member is positioned through the incision.

2. An assembly, as claimed in Claim 1, wherein said means for inserting comprises:

a second elongated member positioned about said first elongated member and having at least one access hole therethrough for receiving suture material.

3. An assembly, as claimed in Claim 2, wherein said second elongated member further comprises:

an expandable portion selectably expandable from a retracted diameter to an expanded diameter larger than said retracted diameter to create a cavity between said first and second elongated members, said cavity being aligned with said at least one opening of said first elongated member.

4. An assembly, as claimed in Claim 3, wherein:

distal movement of a second proximal end of said second elongated member relative to a first proximal end of said first elongated member results in expansion of said expandable portion to said expanded diameter.

5. An assembly, as claimed in Claim 4, wherein:

a second distal end of said second elongated member is secured to a first distal end of said first elongated member and said second proximal end is slidable relative to said first proximal end, and wherein said second elongated member includes longitudinal slits through said expandable portion, whereby distal movement of said second proximal end relative to said first proximal end results in expansion of said expandable portion to form wing portions defining said cavity.

6. An assembly, as claimed in Claim 3, wherein:

said access hole is positioned in a proximal part of said expandable portion.

7. An assembly, as claimed in Claim 3, wherein:

said access hole is misaligned with said opening in said first elongated member when said expandable portion is in said retracted diameter.

8. An assembly, as claimed in Claim 3, wherein:

said access hole, said cavity and said opening define an access path from an exterior of said assembly to said hollow portion when said expandable portion is in said expanded diameter.

9. An assembly, as claimed in Claim 2, wherein said means for inserting comprises:

at least one needle insertable through the tissue wall and through said access hole in said second elongated member.

10. An assembly, as claimed in Claim 9, wherein said means for inserting further comprises:

a third member positioned about said second elongated member and having at least one lumen extending therethrough for receiving and guiding said needle toward said access hole.

11. An assembly, as claimed in Claim 10, wherein said third member is movable axially relative to said second elongated member.

12. An assembly, as claimed in Claim 9, wherein said needle is a hollow needle, wherein said suture material includes a guide tip integral therewith, and wherein said means for inserting comprises:

a cannula for introducing said guide tip through said at least one hollow needle and through said at least one opening.

13. An assembly, as claimed in Claim 9, further comprising:

means, interconnected with said needle, for rotationally orienting said needle relative to said first elongated member.

14. An assembly, as claimed in Claim 13, wherein said means for rotationally orienting comprises:

a stop member attached to a proximal end of said needle.

15. An assembly, as claimed in Claim 1, further comprising:

means, positionable within said hollow portion of said first elongated member, for engaging the suture material within said hollow portion, whereby removal of said engaging member from said hollow portion results in withdrawal of the suture material through the incision.

16. An assembly, as claimed in Claim 1, further comprising:

means, positionable within said hollow portion of said first elongated member, for securing the suture material within said hollow portion, whereby removal of said first elongated member from said incision results in withdrawal of the suture material through the incision.

17. An assembly, as claimed in Claim 16, wherein said means for securing comprises:

a fourth member slidably positionable within said hollow portion, whereby said fourth member is slidable toward said at least one opening to restrict the suture material between said fourth member and said sidewall of said first elongated member to thereby secure the suture material within said hollow portion.

18. An assembly, as claimed in Claim 16, wherein said means for securing comprises:

an expandable member positionable within said hollow portion, whereby said expandable member is

expandable to secure the suture material within said hollow portion.

19. A method for use in suturing an incision in a tissue wall of a patient with a suture material, said method comprising the steps of:

positioning an apparatus through the incision, the apparatus comprising a first elongated member having a hollow portion and an opening through a sidewall adjacent the hollow portion, the opening being positioned distal to the tissue wall;

inserting the suture material through the tissue wall and through the opening of the sidewall; and

withdrawing the suture material through the incision.

20. A method, as claimed in Claim 19, wherein the apparatus further comprises a second elongated member positioned about the first elongated member and including an expandable portion having an access hole therethrough, and wherein said step of inserting the suture material comprises:

expanding the expandable portion of the second elongated member from a retracted diameter to an expanded diameter larger than the retracted diameter to create a cavity between the first and second elongated members, the cavity being aligned with the opening of the first elongated member

21. A method, as claimed in Claim 20, wherein a second distal end of the second elongated member is secured

to a first distal end of the first elongated member and a second proximal end of the second elongated member is slidable relative to a first proximal end of the first elongated member, and wherein the second elongated member includes longitudinal slits through the expandable portion, and wherein said step of expanding an expandable portion comprises:

sliding the second proximal end in a distal direction relative to the first proximal end to cause expansion of the expandable portion to form wing portions defining the cavity.

22. A method, as claimed in Claim 20, wherein said step of inserting the suture material further comprises:

inserting a needle through the tissue wall and through the access hole in the second elongated member.

23. A method, as claimed in Claim 22, wherein said step of inserting a needle further comprises:

inserting the needle through a lumen in a third member positioned about the second elongated member and continuing said inserting step until the needle passes through the tissue wall and through the access hole in the second elongated member.

24. A method, as claimed in Claim 22, wherein the needle is a hollow needle, wherein the suture material includes a guide tip, and wherein said step of introducing the suture material comprises:

pushing the guide tip through the needle with a cannula until the guide tip is forced through the opening and into the cavity.

25. A method, as claimed in Claim 19, wherein said step of withdrawing the suture material through the incision comprises:

removing the first elongated member from the incision.

26. A method, as claimed in Claim 25, further comprising, before said removing step, the step of:

securing the suture material within the hollow portion.

27. A method, as claimed in Claim 26, wherein said step of securing the suture material comprises:

sliding a fourth member, slidably positioned within the interior of the first elongated member, toward the opening to secure the suture material within the hollow portion.

28. A method, as claimed in Claim 26, wherein said step of securing the suture material comprises:

expanding an expandable member, appropriately positioned within the interior of the first elongated member, to secure the suture material within the hollow portion.

29. A method, as claimed in Claim 19, wherein said step of withdrawing the suture material through the incision comprises:

engaging the suture material within the hollow portion with an engaging member; and

pulling the engaging member proximally relative to the first elongated member to withdraw the suture material through the incision.

30. An catheter introducer capable of assisting in suturing an incision in an arterial wall of a patient, said assembly comprising:

a first elongated hollow member having a sidewall and at least one opening through said sidewall, said first elongated member being positionable through the incision with said opening inside the arterial wall;

a second elongated member positioned about said first elongated member and including an expandable portion selectably expandable from a retracted diameter to an expanded diameter larger than said retracted diameter to create a cavity between said first and second elongated members, said cavity being aligned with said at least one opening, and said expandable portion including an access hole therethrough;

a third member positioned about said second elongated member and having at least one lumen extending therethrough in alignment with said cavity;

suture material; and

a needle insertable into said lumen of said third member, through the arterial wall, and through the access hole in said expandable portion to provide a pathway for introduction of suture material into said first elongated

member via said at least one opening, whereby withdrawal of the assembly from the incision results in the suture material being withdrawn through the incision.

31. An assembly, as claimed in Claim 30, wherein said suture material includes a guide tip integral therewith, and wherein said assembly further comprises:

a cannula for introducing said guide tip through said at least one needle, whereby the guide tip may be inserted into said cavity and through said at least one opening into said hollow portion.

32. An assembly, as claimed in Claim 30, wherein said suture material comprises two end portions, each being of a different color than the other.

33. An assembly, as claimed in Claim 30, further comprising:

a fourth member slidably positioned within said interior of said first elongated member, whereby said fourth member is slidable toward said at least one opening to restrict the suture material between said fourth member and said sidewall of said first elongated member to secure the suture material within said hollow portion when said first elongated member is withdrawn from the incision.

34. An assembly for use in suturing an incision in a tissue wall of a patient with a suture material, said assembly comprising:

an elongated member positionable through the incision;

an expandable member positioned about said elongated member, said expandable member being selectably expandable from a retracted diameter to an expanded diameter larger than said retracted diameter to create a cavity between said elongated member and said expandable member; and

means, positionable adjacent to said elongated member, for inserting a suture material through the tissue wall and into said cavity while said elongated member is positioned through the incision.

35. An assembly, as claimed in claim 34, wherein:

distal movement of a second proximal end of said expandable member relative to a first proximal end of said elongated member results in expansion of said expandable member to said expanded diameter.

36. An assembly, as claimed in claim 35, wherein a second distal end of said expandable member is secured to a first distal end of said elongated member and said second proximal end is slidable relative to said first proximal end, and wherein said expandable member includes longitudinal slits through an expandable portion thereof, whereby distal movement of said second proximal end relative to said first proximal end results in expansion of said expandable portion to form wing portions defining said cavity.

37. An assembly, as claimed in claim 34, wherein said expandable member comprises at least one access hole

positioned through a proximal part of said expandable portion.

38. An assembly, as claimed in Claim 37, wherein said means for inserting comprises:

at least one needle insertable through the tissue wall and through said access hole in said expandable member.

39. An assembly, as claimed in Claim 38, wherein said means for inserting further comprises:

an aligning member positioned about said elongated member and having at least one lumen extending therethrough for receiving and guiding said needle toward said access hole.

40 An assembly, as claimed in Claim 39, wherein said aligning member is movable axially relative to said elongated member.

41. An assembly, as claimed in Claim 38, wherein said needle is a hollow needle, wherein said suture material includes a guide tip integral therewith, and wherein said means for inserting further comprises:

a cannula for introducing said guide tip through said at least one hollow needle and into said cavity.

42. An assembly, as claimed in claim 34, wherein said elongated member comprises a hollow portion and at least one opening through a side wall adjacent to said hollow portion, whereby said first elongated member is positionable through the incision with said at least one opening positioned distal to the tissue wall.

43. A method for use in suturing an incision in a tissue wall of a patient with a suture material, said method comprising the steps of:

inserting an elongated member through the incision, said elongated member having a hollow portion and an opening through a side wall adjacent the hollow portion, the opening being positioned distal to the tissue wall; and

positioning the suture material through the opening in the side wall and through the tissue wall adjacent the incision.

44. A method, as claimed in claim 43, wherein said step of positioning the suture material comprises threading the suture material through the opening from an exterior of the elongated member to an interior thereof.

45. A method, as claimed in claim 43, wherein said step of inserting an elongated member is performed before said step of positioning the suture material.

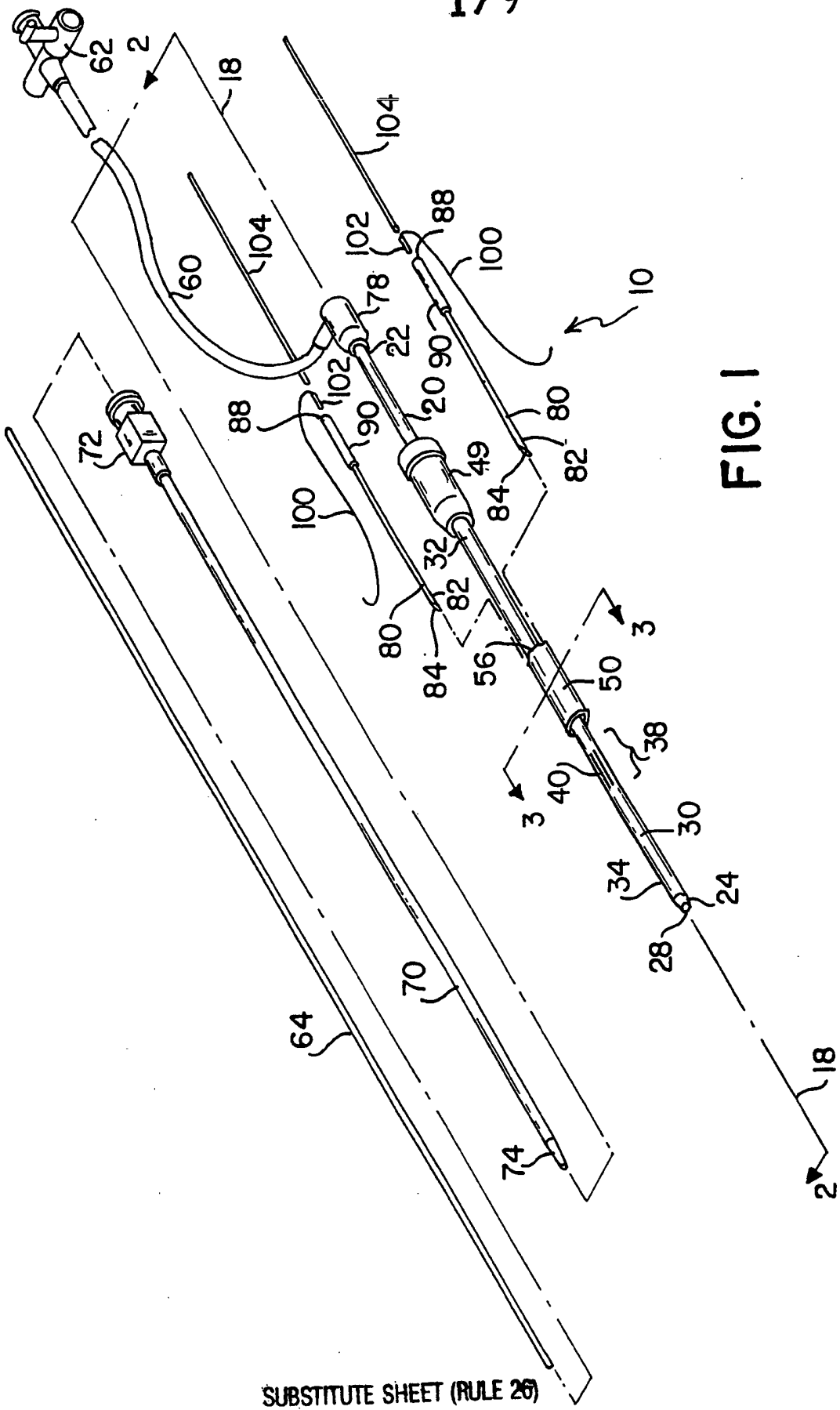
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FIG. 1

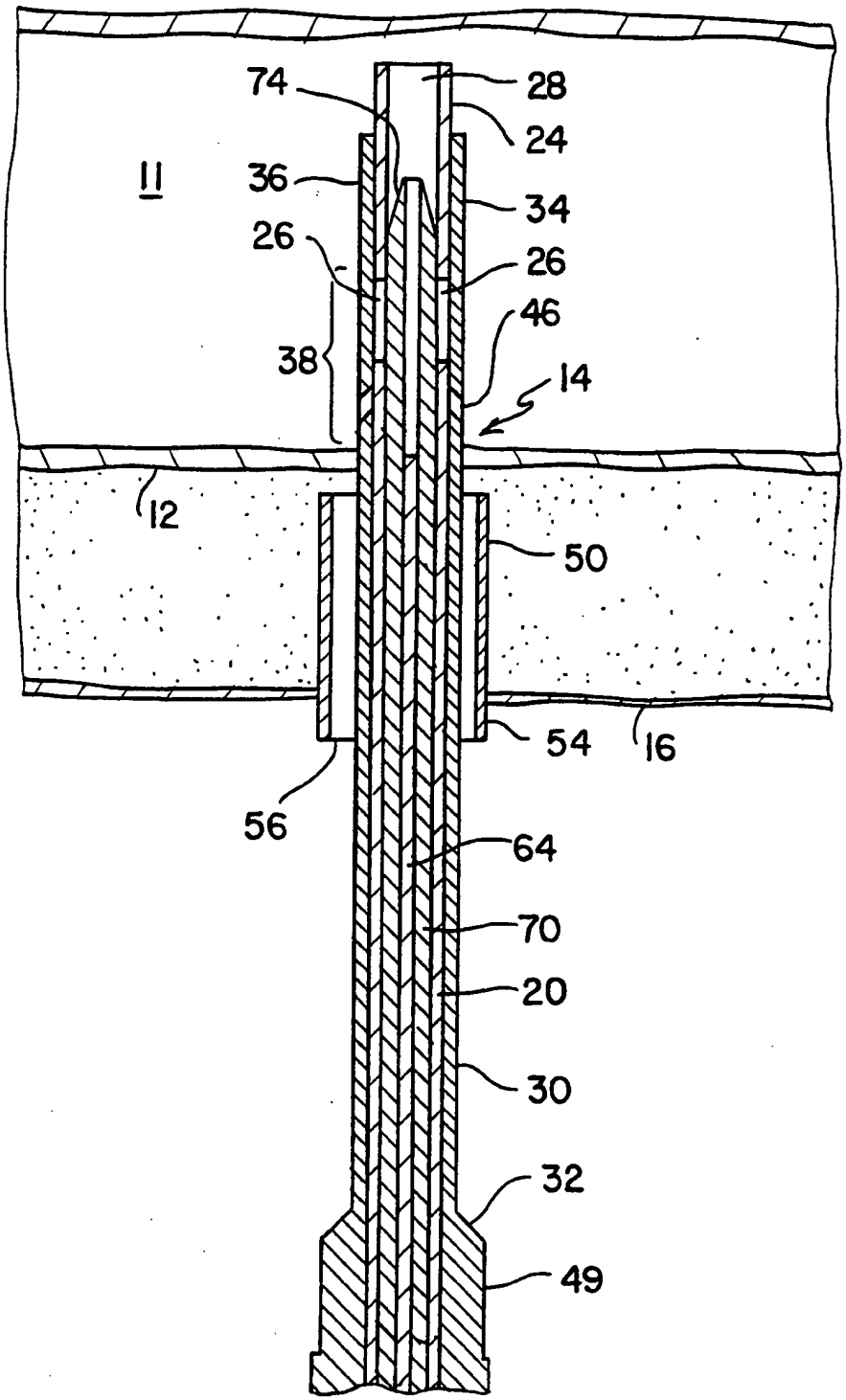

FIG. 2A

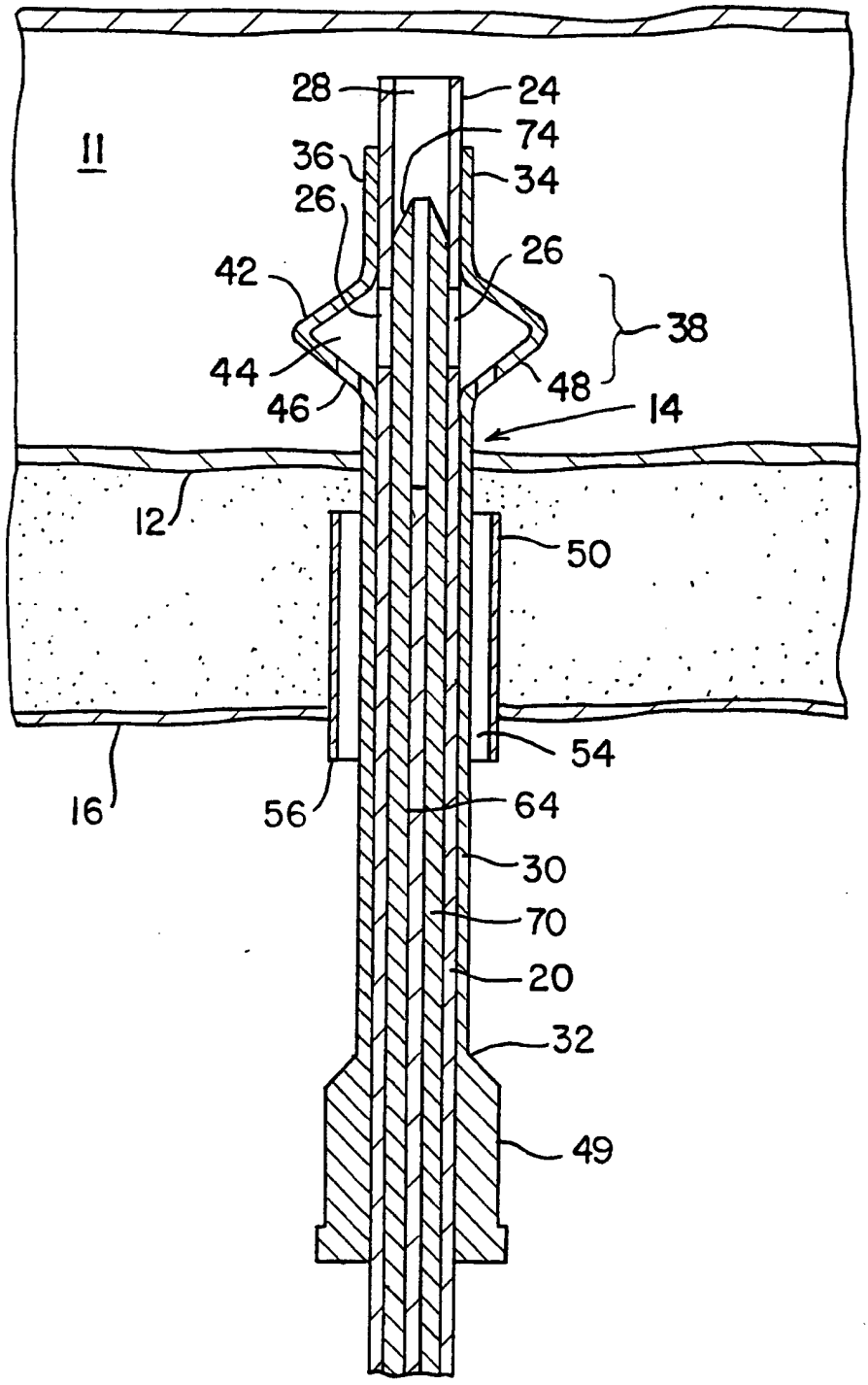
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FIG. 2B

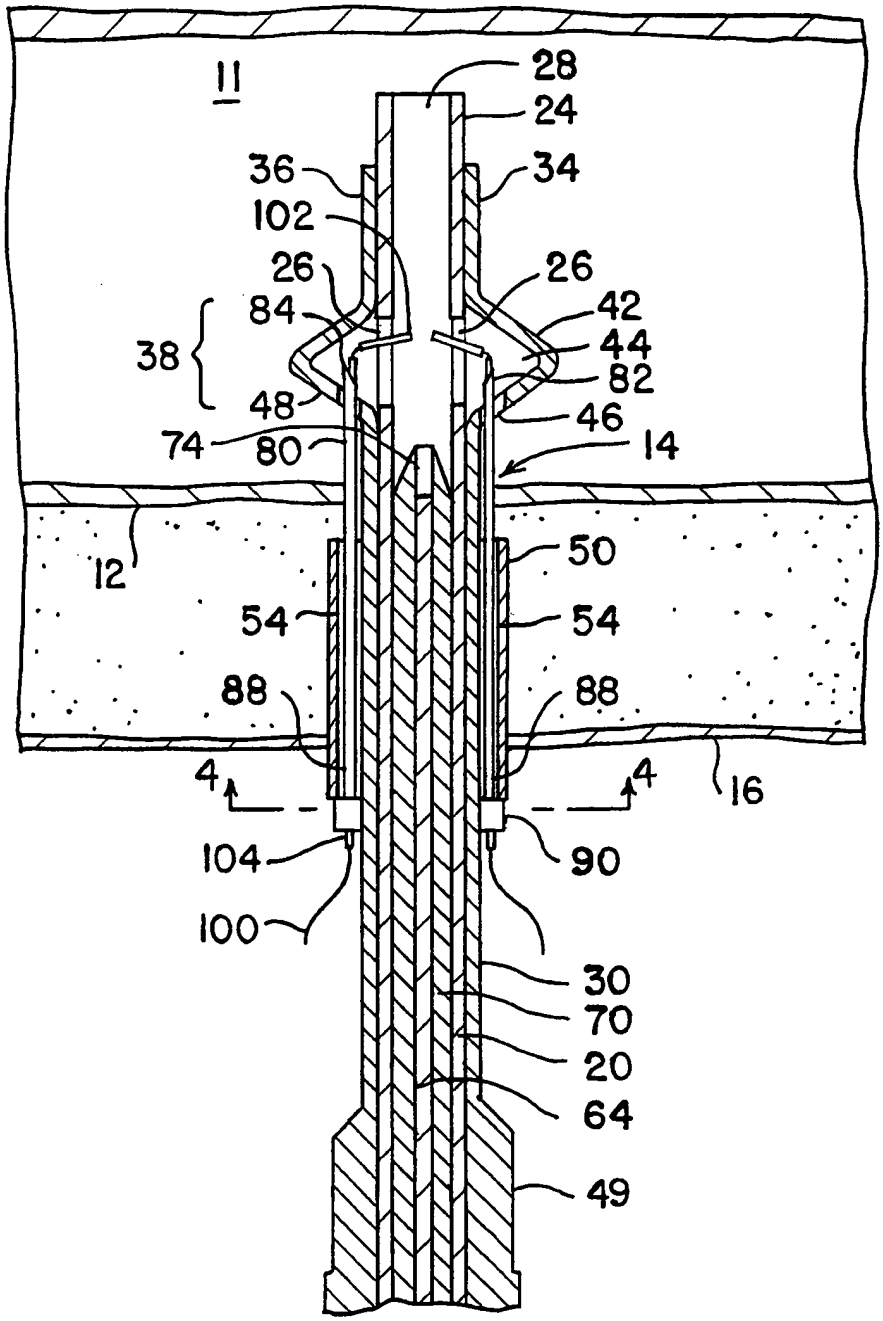
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FIG. 2C

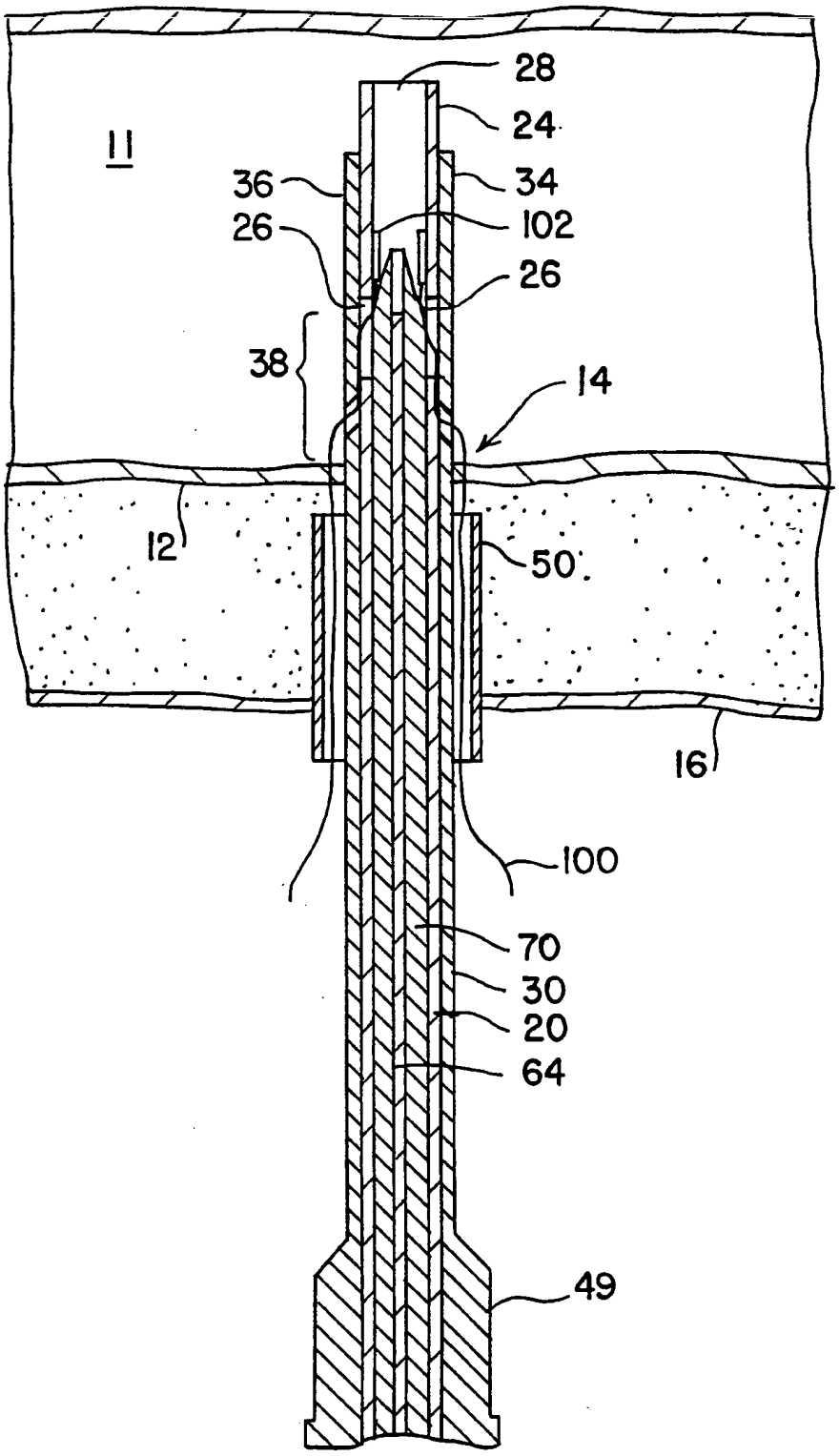

FIG. 2D

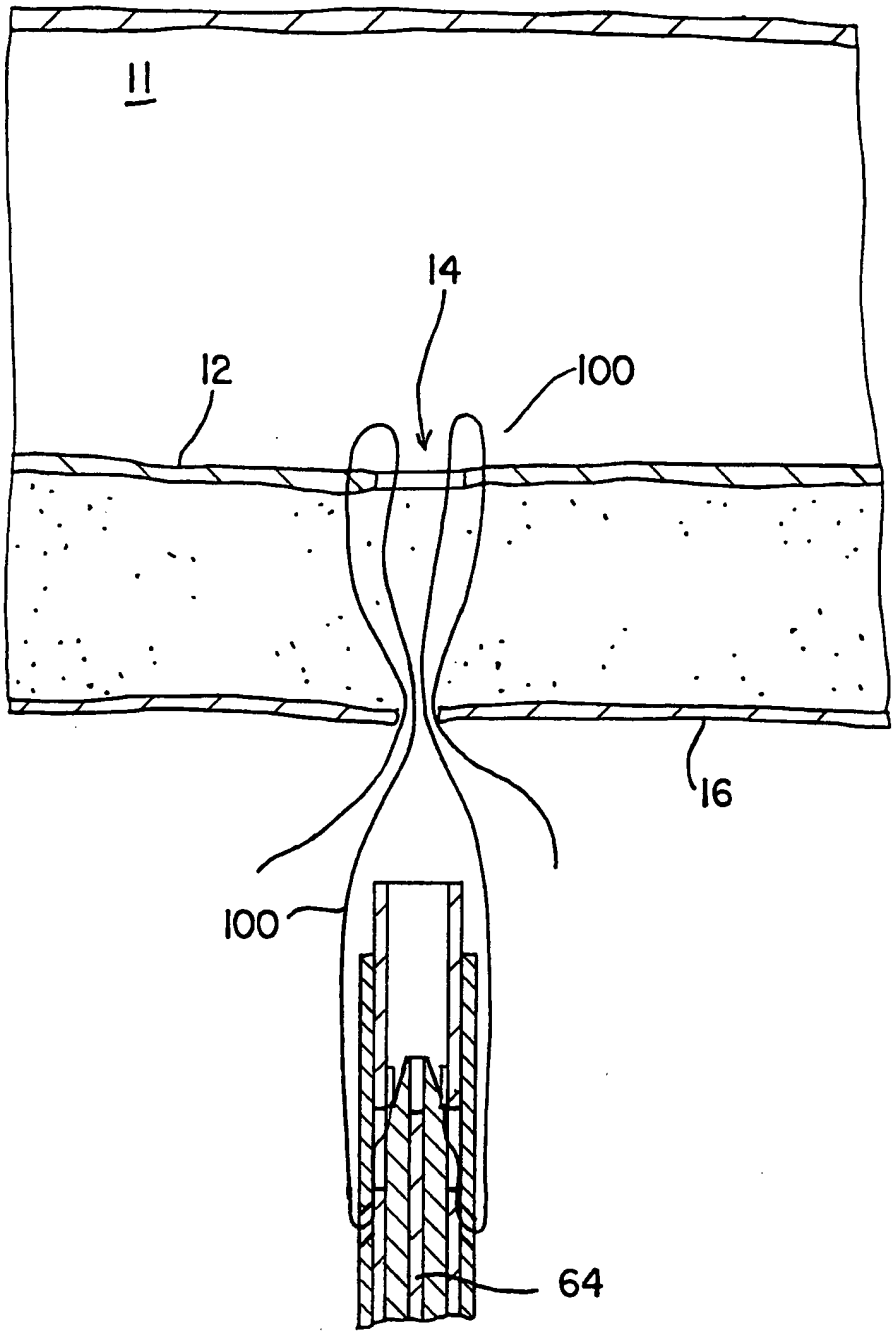

FIG. 2E

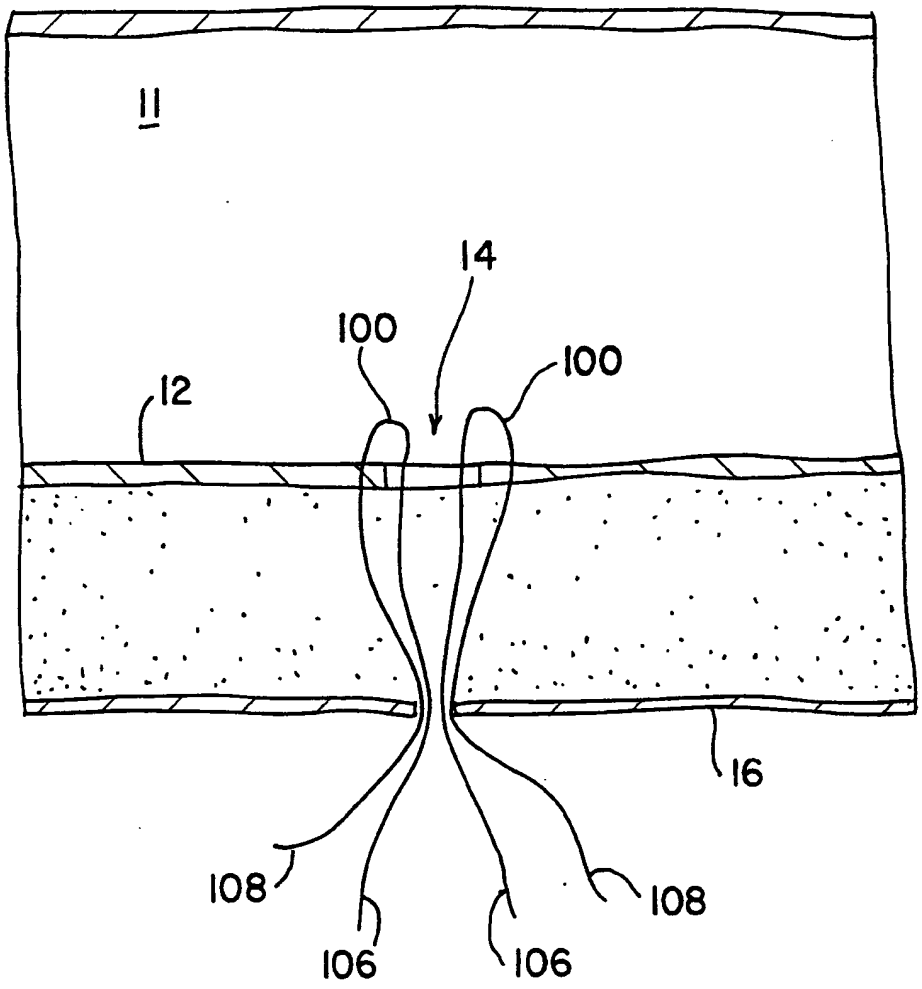

FIG. 2F

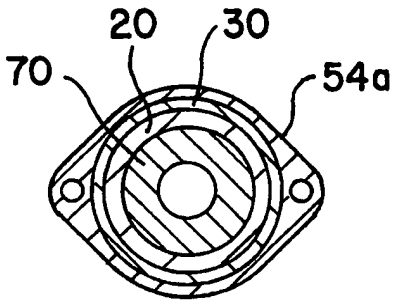

FIG. 3A

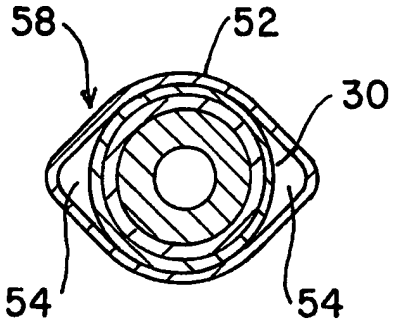

FIG. 3

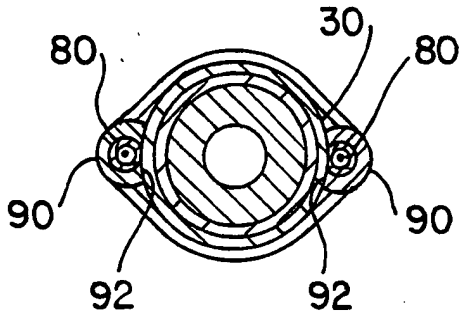

FIG. 4

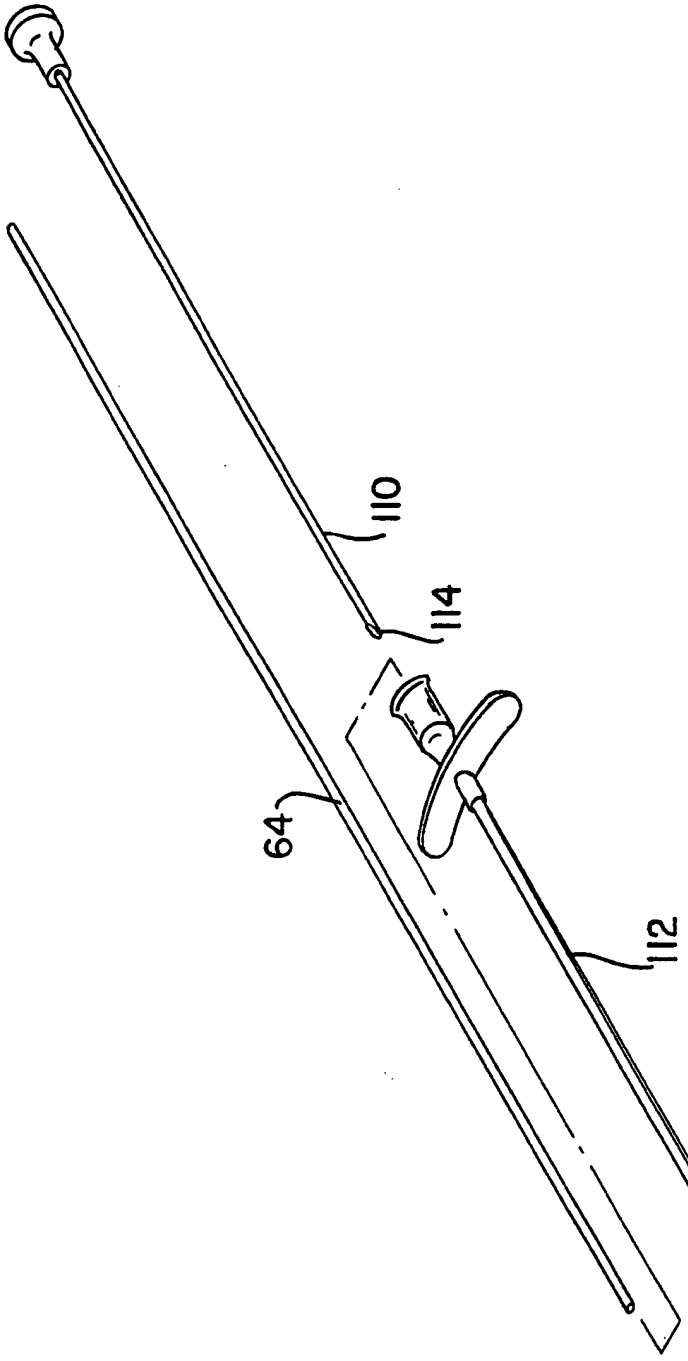

FIG. 5
(PRIOR ART)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/09150

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/04
US CL : 606/139, 144, 148

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 144-148

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,602,635, (MULHOLLAN ET AL.), 29 July 1986. See Figs. 3-7.	1, 2, 19, 29
A	US, A, 5,037,433, (WILK ET AL.), 06 August 1991. See Abstract.	1-29
A, E	US, A, 5,279,551, (JAMES), 18 January 1994. See entire document.	1-29
A, E	US, A, 5,281,234, (WILK ET AL.), 25 January 1994. See all figures.	1-29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

16 NOVEMBER 1994

Date of mailing of the international search report

27 DEC 1994

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Form PCT/ISA/210 (second sheet)(July 1992)*